

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

NUTRAMAX LABORATORIES, INC.	:	
	:	
v.	:	CIVIL NO. CCB-08-879
	:	
JASON THEODOSAKIS, M.D., <i>et al.</i>	:	
	:	
	...o0o...	

MEMORANDUM

Now pending before the court are the motion for summary judgment filed by defendants Jason Theodosakis, M.D. (“Dr. Theodosakis”) and Supplement Testing Institute, Inc. (“STI”) (together “defendants”) and the motion for sanctions filed by plaintiff Nutramax Laboratories, Inc. (“Nutramax”). Nutramax has sued the defendants for patent infringement, and the defendants have moved for summary judgment contending that they have not infringed the plaintiff’s patent and that the patent at issue is invalid. Nutramax also seeks sanctions for the defendants’ alleged spoliation of evidence. The issues have been fully briefed and no hearing is necessary. For the following reasons, the defendants’ motion will be denied,¹ and the plaintiff’s motion will be granted in part and denied in part.

BACKGROUND

Nutramax, a Maryland corporation, manufactures, distributes and sells nutritional supplement products. Dr. Theodosakis, a resident of Arizona, also markets and sells nutritional products that bear his name and endorsement. He is the owner and operator of STI, an Arizona

¹Accordingly, the plaintiff’s motion to strike portions of the defendants’ reply in support of their motion for summary judgment will be denied as moot.

corporation that manufactures and sells nutritional supplement products.

According to Nutramax, it is the assignee of US Patent No. 6,797,289 B2 (the “‘289 patent”) issued by the PTO on September 28, 2004 and titled “Use of anabolic agents, anti-catabolic agents, antioxidant agents, and analgesics for protection, treatment and repair of connective tissues in humans and animals.” The ‘289 Patent contains the following one independent claim and three dependent claims:

Claim 1: A composition for the treatment, repair or prevention of damage to connective tissue comprising: a synergistic combination of an aminosugar and avocado/soybean unsaponifiables [“ASU”].

Claim 2: The composition of claim 1, wherein the aminosugar is selected from the group consisting of glucosamine, glucosamine salts, and mixtures thereof.

Claim 3: The composition of claim 2, wherein the glucosamine salt is selected from the group consisting of glucosamine hydrochloride, glucosamine sulfate, N-acetylglucosamine and salts thereof.

Claim 4: The composition of claim 1, wherein the synergistic combination is administered orally, sublingually, nasally, gutturally, rectally, transdermally, or parenterally.

(*See* U.S. Patent No. 6,797,289.)

The successful ‘289 patent application was a continuation of an application filed March 23, 1999 and initially rejected by the PTO on August 3, 2001. That application claimed: “A composition for the treatment, repair or prevention of damage to connective tissue comprising one or more [ASU] and an aminosugar.” (*See* Defs.’ Summ. J. Mem., Ex. B at 433 (internal alteration omitted).) The PTO examiner found that the claim was anticipated by US Patent No. 5,891,465 (the “Keller patent”), filed on May 14, 1996 and issued on April 6, 1999, which “teaches a composition comprising an aminosugar, glucosamin, and unsaponifiables.” (*See id.* at 442.) The examiner further concluded that the claim was rendered obvious by the Keller patent in combination with other publications, and was indefinite and not adequately described by the specification. (*See id.* at 441-44.)

Nutramax amended its independent claim to require: “A composition for the treatment, repair or prevention of damage to connective tissue comprising: an aminosugar and [ASU]” (*see id.* at 457 (internal alteration omitted)), and submitted expert affidavits discussing studies that found unexpected synergistic effects of the claimed composition. However, the examiner rejected the amended claim citing the same reasons for its previous rejection and noting that the expert affidavits failed to sufficiently explain the proof of results. (*See id.* at 472-75.)

In its successful continuation application, Nutramax further amended the claim to require a “synergistic combination” of ASU and an aminosugar and submitted two new supporting affidavits that further explained the positive results yielded from studies utilizing the claimed synergistic combination (*see* Defs.’ Summ. J. Mem., Ex. A at 170-82).

The defendants manufacture and sell products called “Avosoy Plus” and “Avosoy Complete” (together, the “Avosoy products”) that, according to the plaintiff, compete with Nutramax products containing the claimed composition. Both Avosoy products contain ASU and glucosamine. Avosoy Complete also contains chondroitin. On April 7, 2008, the plaintiff filed suit in this court claiming that the Avosoy products infringe one or more claims of the ‘289 patent. On November 14, 2008, prior to any discovery, the defendants filed their motion for summary judgment contending that the accused products do not infringe the ‘289 patent and that the patent is invalid.

Alleged Spoliation of Evidence

According to the plaintiff, the defendants marketed the Avosoy products on their website, www.drtheo.com, by claiming, *inter alia*, that “Each AVOSOY® product contains the

revolutionary supplement ASU (avocado/soybean unsaponifiables), a unique supplement that synergistically enhances the effects of glucosamine and chondroitin” (the “synergy claim”). The plaintiff further claims that this language, which was on the defendants’ website for at least three years prior to the filing of this lawsuit, was altered to remove the synergy claim after the defendants learned of the plaintiff’s lawsuit. (*See* Pl.’s Mot. for Sanctions, Ex. 5 (attaching archival webpages).)

After the defendants filed their motion for summary judgment, the plaintiff filed document requests seeking, among other things, documents and copies of webpages concerning statements about the combination of ASU and an aminosugar. The defendants did not turn over any information regarding the synergy claim. The plaintiff, however, had seen the synergy claim on the defendants’ website and preserved a copy before the language was removed. On April 6, 2009, the plaintiff filed a motion for sanctions claiming the defendants’ alteration of the website language constituted spoliation of evidence.

ANALYSIS

Rule 56(c) of the Federal Rules of Civil Procedure provides that summary judgment “should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). The Supreme Court has clarified this does not mean that any factual dispute will defeat the motion: “By its very terms, this standard provides that the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is

that there be no *genuine* issue of *material* fact.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) (emphasis in original).

“A party opposing a properly supported motion for summary judgment ‘may not rest upon the mere allegations or denials of [his] pleadings,’ but rather must ‘set forth specific facts showing that there is a genuine issue for trial.’” *Bouchat v. Baltimore Ravens Football Club, Inc.*, 346 F.3d 514, 525 (4th Cir. 2003) (alteration in original) (quoting Fed. R. Civ. P. 56(e)).

The court must “view the evidence in the light most favorable to . . . the nonmovant, and draw all reasonable inferences in her favor without weighing the evidence or assessing the witness’ credibility,” *Dennis v. Columbia Colleton Med. Ctr., Inc.*, 290 F.3d 639, 645 (4th Cir. 2002), but the court also must abide by the “affirmative obligation of the trial judge to prevent factually unsupported claims and defenses from proceeding to trial.” *Bouchat*, 346 F.3d at 526 (internal quotation marks omitted) (quoting *Drewitt v. Pratt*, 999 F.2d 774, 778-79 (4th Cir. 1993), and citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986)).

A. Invalidity

Title 35 U.S.C. § 282 mandates that all patents be presumed valid; the burden of establishing invalidity by clear and convincing evidence rests with the challenging party. *See Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1377 (Fed. Cir. 2002). The defendants challenge the patent on three grounds, which are discussed in turn.

i. Anticipation

Section 102(e) of the Patent Act precludes the granting of a valid patent if “the invention was described in . . . a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent.” Under this standard, a party challenging the validity of a patent as anticipated must show that “each and every limitation of the claimed invention” is present in the prior art reference. *Novo Nordisk Pharmaceuticals, Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1354 (Fed. Cir. 2005). “However, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing feature is necessarily present, or inherent, in the single anticipating reference.” *Id.* at 1355 (internal quotation marks omitted); *see also Rosco*, 304 F.3d at 1380.

The defendants allege that the ‘289 patent is anticipated by the Keller patent. As Nutramax points out, however, the PTO examiner considered the Keller patent during the prosecution of the ‘289 patent. In such a case, the defendants must overcome the deference accorded a government agency responsible for interpreting the prior art at issue. *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1304 (Fed. Cir. 2008) (citing *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984)); *see also Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1348 (Fed. Cir. 2004) (stating that a challenger’s “burden is ‘especially difficult’ when . . . the infringer attempts to rely on prior art that was before the patent examiner during prosecution”).

The defendants, to the contrary, suggest that the court give the examiner’s approval of the ‘289 patent no deference, because, according to the defendants, the examiner applied the wrong law. In essence, the defendants argue that the only explanation for reversing the original finding of anticipation is that the examiner relied on “proof of unexpected results” which, while relevant

to an obviousness determination, is not relevant to a finding of anticipation. (*See* Defs.’ Summ. J. Mem. at 20 & Reply at 17 (both citing *In re Malagari*, 499 F.2d 1297, 1302 (C.C.P.A. 1974).) Looking to the prosecution history, however, the examiner gives no indication that the ultimate decision regarding anticipation relied solely, or even at all, on proof of unexpected results. Rather, the history reveals that Nutramax amended its independent claim to require a “synergistic combination” of ASU and an aminosugar and submitted expert affidavits regarding the efficacy of this method.² Absent some showing, other than the defendants’ own conclusions, that the examiner misapplied the law, the court is not inclined to agree.

Further, the defendants suggest that even if deference is to be shown, “the oversight by the Examiner is undeniable” because of the similarity between the compounds listed in the Keller and ‘289 patents. The defendants, however, merely recite the rationale relied on by the examiner to reject the claims as anticipated by Keller before the claim was amended to require a “synergistic combination.” Despite their heavy burden in proving invalidity, the defendants offer no expert opinion to support a finding that the amended claim was anticipated by the Keller patent and that the agency expert’s finding to the contrary was clearly erroneous. *Cf. Biotec Biologische Naturverpackungen GmbH & Co. v. Biocorp, Inc.*, 249 F.3d 1341, 1353 (Fed. Cir. 2001) (explaining that conclusory statements regarding a patent’s invalidity do not raise a genuine issue of fact).

In short, the current record does not establish by clear and convincing evidence that the

²While those affidavits discussed the unexpected synergistic effect of the claimed combination, the examiner relied on those findings to overcome the initial finding of obviousness (*see* Defs.’ Summ. J. Mem., Ex. A at 184); there is no indication that the examiner relied on proof of unexpected results to reverse the finding on anticipation.

‘289 patent is invalid as anticipated; thus, the defendants are not entitled to summary judgment on this claim.

ii. Proof of Unexpected Results

The defendants also suggest that the claims of the ‘289 patent are invalid because they are broader than the proof of unexpected results Nutramax submitted to rebut the examiner’s initial finding of obviousness. *See In re Greenfield*, 571 F.2d 1185, 1189 (C.C.P.A. 1978) (stating that in order to establish unexpected results for a claimed invention, “objective evidence of non-obviousness must be commensurate in scope with the claims which the evidence is offered to support”) (internal quotations omitted). Specifically, they claim that the plaintiff’s research was limited to experiments involving a limited number of compounds and certain types of connective tissue, but the research was “mistakenly” used to support a claim covering a broader spectrum of compounds and connective tissues. (Defs.’ Summ. J. Mem. at 23.) As with the anticipation claim, however, the defendants offer no expert opinion to support this assertion.

The defendants rely instead on cases from the Federal Circuit and its predecessor, the Court of Customs and Patent Appeals, holding that evidence of unexpected results was inadequate proof of the particular claims at issue. These cases, however, are factually and procedurally distinguishable. First, all of the cases involve different subject matter, making their conclusions based on evidence of different compounds and technologies difficult to extrapolate without some showing that they provide a valid comparison.³ Again, the defendants have offered

³The defendants cite to *In re Peterson*, 315 F.3d 1325 (Fed. Cir. 2003) (involving a composition including rhenium useful in improving an alloy’s mechanical strength without reducing its hot corrosion resistance); *In re Grasselli*, 713 F.2d 731 (Fed. Cir. 1983) (involving

no evidence, aside from their uncorroborated conclusions, to suggest that the tests involved in this application could not cover a broader range of compounds and connective tissues. Second, all of the cases involve challenges to the PTO's *rejection* of claims. Here, on the other hand, the PTO examiner – an agency expert – concluded, in light of the amendments and expert affidavits, that the claimed combination was not obvious over the prior art. (*See* Defs.' Summ. J. Mem., Ex. A at 184.) The defendants cannot merely conclude that the approved claim is incommensurate with the evidence; they must demonstrate clear and convincing evidence of that assertion to overcome the presumption of validity. On the current record, they have failed to meet their burden.

iii. Indefiniteness

Finally, the defendants contend that the '289 patent is invalid for indefiniteness because the application's specification does not conclude with claims "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." *See* 35 U.S.C. § 112, para. 2. In determining whether a claim is definite, courts analyze "whether one skilled in the art would understand the bounds of the claim when read in light of the specification. . . . If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more." *Personalized Media*

Commc'ns, LLC v. Int'l Trade Comm'n, 161 F.3d 696, 705 (Fed. Cir. 1998) (internal quotations

catalysts containing an alkali metal as an essential catalytic ingredient); *In re Clemens*, 622 F.2d 1029 (C.C.P.A. 1980) (involving a method of purifying condensate water for steam regenerating equipment); *Greenfield*, 571 F.2d 1185 (involving a paint composition comprising an acrylic polymer in a water carrier and formaldehyde); *In re Lindner*, 457 F.2d 506 (C.C.P.A. 1972) (involving dispersant compositions designed to emulsify solutions such as insecticide).

omitted).

The defendants, relying on dictionary entries, suggest that the term “synergistic” is ambiguous because it could mean either that the combination of the drugs has an additive or a super-additive effect. As the plaintiff points out, however, the defendants do not provide evidence of how “one skilled in the art” would define “synergistic” in light of the patent claims and specification. *See Kinetic Concepts, Inc. v. Blue Sky Med. Group, Inc.*, 554 F.3d 1010, 1022 (Fed. Cir. 2009). And the defendants offer no compelling explanation for why the examiner, who is deemed to be one of ordinary skill in the art, did not consider the term “synergistic” in the context of the specification to be ambiguous. It is not enough merely to conclude that a reasonable interpretation of the term could be ambiguous; the defendants must demonstrate that the term is “insolubly ambiguous.” *Id.* In other words, “[i]f the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree,” the claim is not invalid on indefiniteness grounds. *Id.* (citing *Exxon Research & Eng’g Co. v. U.S.*, 265 F.3d 1371, 1375 (Fed. Cir. 2001)). In light of the presumption of validity and without some showing that a person skilled in the art would not be able to discern the meaning of the term at issue, the defendants have failed to meet their summary judgment burden.

B. Infringement and Sanctions

In their motion for summary judgment, the defendants contend that the plaintiff has no proof that the accused brand of Avosoy products contains a synergistic combination of the

specified compounds and, thus, cannot defeat their motion for summary judgment. The plaintiff asserts, in opposition, that the advertising claim on the defendants' website touting the synergistic effect of ASU on glucosamine is an admission of infringement and sufficient evidence to survive the defendants' motion to dismiss.⁴ The defendants submit that the advertising language is not evidence of infringement and that, even if it were, it is not sufficient on its own to defeat their motion for summary judgment.⁵

At the outset, the record demonstrates that the defendants removed this language from the website sometime after learning of the plaintiff's lawsuit and prior to submitting their motion for summary judgment.⁶ Moreover, the defendants did not turn over any evidence of the synergy claim in response to plaintiff's requests for "any advertising, marketing or promotional statements that You have made about the Avosoy Products or about the combination of [ASU] and an aminosugar (including glucosamine), regardless of the method or medium in which such statements were made)" or for copies of webpages referencing the combination of ASU and an aminosugar. (*See* Pl.'s Mot. for Sanctions at 6-7 (citing document requests and counsel communications).) The plaintiff contends that the website alteration constitutes spoliation of

⁴The plaintiff relies heavily on *Johnson & Johnson v. Carolina Lee Knitting Co.*, 258 F.2d 593, 599 (4th Cir. 1958), which noted that "[w]hile advertising claims alone may not be sufficient to make out a case for infringement, . . . the Courts have in numerous instances relied on advertisements as admissions by the defendant of the infringing nature of the accused product."

⁵In light of the defendants' conduct regarding the synergy claim and the appropriate sanction, discussed below, the court will not entertain these arguments on the current record. The defendants are free to reassert these arguments at a later stage of the litigation, as appropriate.

⁶(*Compare* Pl.'s Mot. for Sanctions Ex. 2 (showing synergy claim on www.drtheos.com on September 3, 2008) *with id.* Ex. 5, tab 1 (showing altered language without synergy claim on October 24, 2008).)

evidence and asks the court to sanction the defendants accordingly.

Describing what constitutes spoliation, the court has explained:

A party has a duty to preserve evidence when the party is placed on notice that the evidence is relevant to litigation or when the party should have known that the evidence may be relevant to future litigation. The duty to preserve encompasses any documents or tangible items authored or made by individuals likely to have discoverable information that the disclosing party may use to support its claims or defenses. Any information relevant to the claims or defenses of any party, or which is relevant to the subject matter involved in the litigation, is covered by the duty to preserve. . . .

A failure to preserve documents and records, once the duty to do so has been triggered, raises the issue of spoliation of evidence. Spoliation refers to the destruction or material alteration of evidence or the failure to preserve the property for another's use as evidence in pending or reasonably foreseeable litigation. A court has discretion to impose sanctions for the purpose of leveling the evidentiary playing field and for the purpose of sanctioning the improper conduct. The court should, therefore, take into account the blameworthiness of the offending party and the prejudice suffered by the opposing party.

Broccoli v. Echostar Commc'ns Corp., 229 F.R.D. 506, 510 (D. Md. 2005) (internal citations and quotations omitted).

The defendants suggest that there was no spoliation because the information on the website was preserved in a public archive such that the plaintiff was able to access it. Such a suggestion is belied not only by the defendants' failure to offer up the statement in response to the plaintiff's requests for such advertising claims, but also by the underlying purpose of the court's discretionary power to sanction – "the need to preserve the integrity of the judicial process in order to retain confidence that the process works to uncover the truth." *Silvestri v. Gen. Motors Corp.*, 271 F.3d 583, 590 (4th Cir. 2001). While the adversarial process imposes investigatory burdens on both parties, a party cannot hide or alter evidence in an attempt to escape liability and then seek to avoid sanctions by relying on the opposing party's good fortune in discovering that evidence.

Turning, then, to the elements of spoliation, in light of the timing – the defendants

removed the evidence at issue *after* learning of the plaintiff's lawsuit – there is no question that the defendants' duty to preserve was triggered. Such a duty would certainly extend to relevant advertising claims on a website touting and explaining the efficacy of the accused product. The similarity of the synergy claim to the language of the '289 patent suggests that it is relevant to the legal claims at issue. The timing of the defendants' conduct further suggests that they knew the advertising language was relevant to the plaintiff's claims and that is precisely why they removed it.⁷

Nonetheless, the defendants suggest that the plaintiff has not been prejudiced because Nutramax was able to access the advertising claim. The defendants' highly questionable conduct, however, suggests that there may be other evidence relevant to this summary judgment motion that has yet to surface. As the plaintiff points out, it is reasonable to assume that the defendants' synergy claim would be supported by some evidence. Therefore, to level the evidentiary playing field and to sanction the defendants' improper conduct, the court will deny their summary judgment motion without prejudice to permit discovery on the infringement claim.⁸ Such a sanction is appropriate in light of the defendants' conduct. *See Silvestri*, 271 F.3d at 590 (noting the district court's broad discretion in crafting an appropriate sanction to best "serve the

⁷The defendants suggest that they removed the synergy claim from the website because studies revealed that the touted synergistic effect of ASU on glucosamine and chondroitin was false. These studies, however, were known to the defendants months before they removed the synergy claim and, as recently as May 5, 2009, the defendants' website documented why at least one of these studies is invalid (*see* Pl.'s Reply in Support of Mot. for Sanctions, Ex. A, tab 1). Moreover, the defendants' failure to turn over a copy of the webpage containing the synergy claim in response to the plaintiff's requests raises serious doubts about the defendants' proffered justification.

⁸The plaintiff's motion for sanctions is denied as to any other specific relief requested.

prophylactic, punitive, and remedial rationales underlying the spoliation doctrine”). The denial of the defendants’ motion notwithstanding, the plaintiff retains the burden, after discovery, of putting forth sufficient evidence to prove its claim of infringement.

CONCLUSION

For the foregoing reasons, the court will deny the defendants’ motion for summary judgment as to all invalidity claims. Further, the court will grant the plaintiff’s motion for sanctions and, accordingly, will deny the defendants’ motion for summary judgment on the infringement claim to permit further discovery on the issue. A separate order follows.

June 8, 2009
Date

/s/
Catherine C. Blake
United States District Judge

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

NUTRAMAX LABORATORIES, INC.	:	
	:	
v.	:	CIVIL NO. CCB-08-879
	:	
JASON THEODOSAKIS, M.D., <i>et al.</i>	:	
	:	
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ORDER

For the reasons stated in the accompanying Memorandum, it is hereby **ORDERED** that:

1. the defendants' motion for summary judgment (docket entries no. 22 and 23) is

DENIED;

3. the plaintiff's motion for sanctions (docket entry no. 48) is **GRANTED in part** and

DENIED in part; and

2. the plaintiff's motion to strike (docket entry no. 53) is **DENIED** as moot.

June 8, 2009
Date

/s/
Catherine C. Blake
United States District Judge